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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket Nos. FDA-2013-N-0683, FDA-2013-N-0684, and FDA-2013-N-0685]

Food and Drug Administration Safety and Innovation Act Title VII--Drug Supply Chain;
Standards for Admission of Imported Drugs, Registration of Commercial Importers and Good
Importer Practices; Notification of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting regarding FDA's implementation of Title VII of the Food and Drug Administration Safety and Innovation Act (FDASIA), which provides FDA with important new authorities to help it better protect the integrity of the drug supply chain. In addition to providing a general overview of Title VII and FDA's approach to implementing these provisions, the meeting will give interested persons an opportunity to provide input that will assist FDA in the development of regulations implementing two sections of Title VII, which relate to standards for admission of imported drugs and commercial drug importers. Specifically, FDA is seeking information on the types of information that importers should be required to provide under Title VII as a condition of admission. FDA is also seeking information regarding registration requirements for commercial drug importers and good importer practices to be established under Title VII.

DATES: The public meeting will be held on July 12, 2013, from 9 a.m. to 5 p.m. at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room

(rm. 1503), Silver Spring MD 20993. Please note that visitors to the White Oak Campus must enter through Building 1. The White Oak Campus location is a Federal facility with security procedures and limited seating. There is no fee to register for the meeting and registration will be on a first come, first serve basis. Early registration is recommended because seating is limited. Onsite registration will also be permitted if there is available space. See section IV of this document, "How to Participate in the Public Meeting," for the date and time of the public meeting and closing dates for advance registration.

FOR FURTHER INFORMATION CONTACT: Susan DeMars, Office of Global Regulatory Operations and Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3302, Silver Spring, MD 20993, 301-796-4635, email: susan.demars@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The globalization of the pharmaceutical market has created tremendous challenges for FDA, including dramatic increases in drug imports, complex and fragmented global supply chains, and increasing threats of fraudulent and substandard drugs. Title VII of FDASIA (Public Law 112-144) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to provide FDA with important new authorities to respond to these challenges and better ensure the safety, effectiveness, and quality of drugs imported into the United States. These authorities increase FDA's ability to collect and analyze data to make risk-informed decisions, employ risk-based approaches to facility oversight, partner with foreign regulatory authorities to leverage resources through information sharing and recognition of foreign inspections, and drive safety and quality throughout the supply chain. Implementation of these authorities will significantly advance the strategies set forth in the Pathway to Global Product Safety and Quality report published by FDA

(available at

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/GlobalProductPathway/UCM262528.pdf>), and accelerate the Agency's adaptation to

the rapidly changing demands of the global environment. Implementation of these authorities will also support and advance FDA's ongoing industry oversight of quality related initiatives.

At the same time, implementation of Title VII of FDASIA is difficult and complex, and requires not only the development of new regulations, guidances, and reports, but also major changes in FDA information systems, processes, and policies. Since the enactment of FDASIA in July 2012, FDA has been working diligently to implement the provisions of Title VII and has prioritized these efforts based on public health impact in order to maximize use of the Agency's limited resources.

Sections 713 and 714 in Title VII of FDASIA relate to drugs imported or offered for import and commercial drug importers. Section 713 allows FDA to require, as a condition of granting admission to a drug imported or offered for import into the United States, that an importer electronically submit information demonstrating that the drug complies with applicable requirements of the FD&C Act. As specified in section 713, such information may include: Information demonstrating the regulatory status of the drug, such as the new drug application number, abbreviated new drug application number, investigational new drug number, or drug master file number; facility information, such as proof of registration and the unique facility identifier; indication of compliance with current good manufacturing practice (CGMP), testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations; and any other information deemed necessary and appropriate by the Secretary to assess compliance. Section 713 also allows FDA to take into account differences among

importers and types of imported drugs and, based on the level of risk posed by the imported drug, provide for expedited clearance for those importers that volunteer to participate in partnership programs for highly compliant companies and pass a review of internal controls, including sourcing of foreign manufacturing inputs, and plant inspections. Section 713 requires FDA to adopt regulations implementing section 713 not later than 18 months after the date of enactment of FDASIA.

Section 714 requires commercial drug importers to register with FDA and submit a unique identifier for the principal place of business at the time of registration. FDA is to specify a unique facility identifier system to be used by registrants. Section 714 amends section 502(o) of the FD&C Act (21 U.S.C. 352(o)) to deem misbranded a drug imported or offered for import by a commercial importer of drugs not duly registered. Section 714 also requires FDA, in consultation with the Secretary of the Department of Homeland Security acting through U.S. Customs and Border Protection, to issue regulations establishing good importer practices that specify the measures an importer shall take to ensure that imported drugs are in compliance with the FD&C Act and the Public Health Service Act. Section 714 requires FDA to adopt regulations implementing section 714 not later than 36 months after the date of enactment of FDASIA.

The public meeting is an opportunity for FDA to share information regarding Title VII and the Agency's approach to implementation, and to obtain input from stakeholders that will assist FDA in developing regulations under sections 713 and 714.

II. Purpose and Format of Meeting

The first part of the public meeting will consist of introductory presentations by FDA that will provide an overview to stakeholders regarding Title VII, including the new authorities granted to FDA under Title VII and their importance in ensuring drug safety, effectiveness, and

quality; how Title VII relates to and will help advance FDA's larger strategic initiatives; the Agency's approach to implementation; and the progress achieved to date.

The second part of the meeting will be used to obtain input from stakeholders on issues relating to standards for admission of imported drugs, registration of commercial importers, and good importer practices that will assist FDA in the development of the regulations described previously. Individuals will have opportunities to express their views by making presentations at the meeting and submitting written comments to the dockets for these matters (see section V of this document).

III. Scope of Public Input Requested

FDA is particularly interested in obtaining information and public comment on the following topics:

A. Section 713: Standards for Admission of Imported Drugs

1. How should the regulations implementing section 801(r) of the FD&C Act (21 U.S.C. 381(r)), as amended by section 713 of FDASIA, define "importer" as that term is used in 801(r)(l)?
2. What information should FDA require importers to submit at the time of entry that would demonstrate a drug's compliance with applicable requirements of the FD&C Act as a condition of granting admission of the drug into the United States?
3. What information could an importer submit to FDA at the time of entry to demonstrate compliance with applicable requirements of the FD&C Act relating to:
 - a. homeopathic drugs intended for human use,
 - b. articles intended for human drug compounding,
 - c. articles intended for animal drug compounding, and

- d. drugs intended for research?
- 4. What facility information should FDA request from importers at the time of entry to help assess whether a drug complies with applicable requirements of the FD&C Act?
- 5. What information could importers submit at the time of entry to demonstrate compliance with country of export regulations in accordance with section 801(r)(2)(C) of the FD&C Act?
- 6. What information could importers submit at the time of entry to demonstrate that a drug offered for import complies with U.S. CGMP requirements?
- 7. What information could importers submit at the time of entry that would serve as evidence of satisfactory inspection, such as by a foreign government or an agency of a foreign government?
- 8. Should FDA require that importers submit certificates of analysis (COAs) to the Agency as a condition of admission under section 801(r) of the FD&C Act? If so, how could an importer demonstrate a COA's authenticity?
- 9. Section 801(r)(4)(B)(i) of the FD&C Act permits FDA, as appropriate, to consider differences among imports and types of drugs and "based on the level of risk posed by the imported drug, provide for expedited clearance for those importers that volunteer to participate in partnership programs for highly compliant companies and pass a review of internal controls, including sourcing of foreign manufacturing inputs, and plant inspections."
 - a. What criteria should FDA use to evaluate potential participants in "voluntary partnership programs for highly compliant companies"?

- b. How could FDA take into account differences among importers and types of drugs to allow for expedited entry as part of a voluntary partnership program?
 - c. What risk factors should FDA consider when determining drug admissibility under a voluntary partnership program?
10. What benefits and burdens may be created by requiring drug importers to electronically submit information demonstrating that a drug complies with applicable requirements of the FD&C Act as a condition of admission? How could we minimize any possible burdens? How do we strike a reasonable balance between rigor and efficiency in requiring information that is both reliable and yet can be submitted and reviewed efficiently?

B. Section 714: Registration of Commercial Importers of Drugs

1. How should the regulations implementing section 714 of FDASIA (section 801(s) of the FD&C Act) define "commercial importer" to ensure that the appropriate entities are required to register with FDA and meet requirements regarding good importer practices (GIP)? Should these "commercial importers" be the same entities as the "importers" required to comply with the standards for admission to be adopted under section 801(r) of the FD&C Act?
2. Under section 801(s)(1) of the FD&C Act, the registration regulations will apply to commercial importers of "drugs." A "drug" is defined in section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)) and includes, but is not limited to, finished dosage form drug products, drugs for further processing, active pharmaceutical ingredients, and other drug components, including inactive ingredients. Should commercial importers of certain types of drugs, such as inactive ingredients, be exempt from the commercial importer

registration requirements? Should the importation of drugs for certain purposes (e.g., research use) be exempt from registration?

3. What information should commercial importers be required to submit as part of their registration?
4. What benefits and burdens might be created by requiring commercial drug importers to register with FDA? How can we minimize any possible burdens (e.g., through gradual implementation, exemption of certain commercial importers, use of other alternatives)?

C. Section 714: Good Importer Practices

1. How might FDA structure the GIP regulations to avoid imposing redundant regulatory requirements on commercial importers that also are drug manufacturers and therefore would be subject to both the GIP and CGMP requirements?
2. Should the GIP regulations require commercial importers of drugs to establish drug safety management programs to ensure that imported drugs meet the requirements of the FD&C Act and the Public Health Service Act, as applicable? If so, what matters (e.g., procedures, personnel) should the GIP regulations require commercial importers to address in such programs?
3. What drug safety management programs or other measures do commercial importers currently have in place to ensure that imported drugs are manufactured in compliance with applicable FDA requirements? How do these programs and measures differ for different "types" of drugs?
4. Should the GIP regulations include qualifications and training for personnel who perform GIP activities? If so, what qualifications and training should be required?

5. Should the GIP regulations include a requirement for commercial importers to assess whether it is appropriate to import a particular drug from a particular foreign supplier? If so, what information on the drug and the supplier should the commercial importer be required to consider as part of this assessment?
6. Should commercial importers be required to conduct activities to verify that a drug that is offered for import is in compliance with applicable U.S. requirements (e.g., the CGMP regulations) and are not adulterated under section 501 of the FD&C Act (21 U.S.C. 351) or misbranded under section 502 of the FD&C Act? If so, what supplier verification activities should commercial importers be required to conduct?
7. Should there be different supplier verification or other GIP requirements for different "types" of drugs? Should there be different requirements for particular types of finished dosage form drug products that might be associated with different levels of risk (e.g., sterile injectables, drugs that require temperature controls)? If so, what should these requirements be?
8. Should the GIP regulations require commercial importers to obtain a COA for each imported drug? Should such a requirement apply only to certain types of drugs or commercial importers? If commercial importers are required to obtain COAs, should the commercial importer also be required to conduct testing to verify the accuracy of the COA?
9. Should the GIP regulations include specific requirements for drugs imported for export in accordance with section 801(d)(3) of the FD&C Act? If so, what should these requirements be?

10. How should the GIP regulations reflect or incorporate the requirements concerning the standards for admission of imported drugs under section 801(r) of the FD&C Act? For example, should the GIP requirements include the adoption of procedures to ensure that the commercial importer submits the compliance information required under section 801(r) and the regulations implementing that section? If so, what procedures should commercial importers be required to follow to ensure that these requirements are met?
11. Should the GIP regulations require commercial importers to take corrective actions when the drugs they import or offer for import are not in compliance with applicable U.S. requirements? If so, what actions should importers be required to take?
12. Should the GIP regulations include a requirement for commercial importers to list the drugs they import or offer for import? If so, what information should be required with listing?
13. What records should commercial importers be required to maintain under the GIP regulations?
14. What other matters, if any, should the GIP regulations address?
15. How should FDA take into account "differences among importers and types of imports, including based on the level of risk posed by the imported product," in determining reasonable time periods for commercial importers to come into compliance with the GIP regulations under section 714(d)(3) of FDASIA? In considering such differences, how should FDA determine the level of risk posed by an imported drug?
16. What benefits and burdens might be created by requiring commercial importers to comply with GIP regulations? How can we minimize any possible burdens (e.g., through

gradual implementation, exemption of certain commercial importers, use of other alternatives)?

IV. How to Participate in the Public Meeting

Individuals who wish to present at the public meeting must register on or before July 5, 2013, through the FDASIA Web site at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm20027187.htm> and provide complete contact information, including name, title, affiliation, address, email, and phone number. In section III of this document, FDA has included questions for comment. You should identify by number each question you wish to address in your presentation, provide a brief description of your presentation, and indicate the approximate desired length of your presentation, so that FDA can consider these in organizing the presentations. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. After reviewing the presentation requests, FDA will notify each participant before the meeting of the amount of time available and the approximate time their presentation is scheduled to begin. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make a presentation. An agenda will be posted on the FDASIA Web site at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm20027187.htm> prior to the meeting.

Table 1 of this document provides information on participating in the meeting and on submitting comments to the docket. See table 2 of this document for a list of docket numbers and corresponding sections of FDASIA and topics.

Table 1.--Information on Participation in the Meeting and on Submitting Comments

	Date	Electronic Address	Address (non-electronic)	Other Information
Date of public meeting	July 12, 2013, 9 a.m. to 5 p.m.		FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993	Onsite registration begins at 7:30 a.m.
Advance registration	By July 5, 2013	http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAct/SignificantAmendments/totheFDCA/FDA/SIA/ucm20027187.htm		Registration will also be accepted onsite on the day of the meeting, as space permits.
Request special accommodations due to disability	By July 5, 2013		Susan DeMars, 301-796-4635, email: susan.demars@fda.hhs.gov	
Make a request for an oral presentation and provide a brief description of the oral presentation	By July 5, 2013	http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAct/SignificantAmendments/totheFDCA/FDA/SIA/ucm20027187.htm		Requests made on the day of the meeting to make an oral presentation may be granted as time permits. Information on requests to make a presentation, including any personal information provided, may be posted without change to http://www.regulations.gov .
Submit electronic or written comments	By August 12, 2013	Federal eRulemaking Portal: http://www.regulations.gov . Follow the instructions for submitting comments.	FAX: 301-827-6870. Mail/Hand-delivery/Courier: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.	All comments must include the Agency name and the docket number corresponding with the section of FDASIA and topic on which you are commenting (see table 2 for a list of docket numbers and corresponding sections of FDASIA and topics). All received comments, including any personal information provided, may be posted without change to http://www.regulations.gov . FDA encourages the

				submission of electronic comments by using the Federal eRulemaking Portal.
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V. Comments

Regardless of attendance at the public meeting, interested persons may submit either electronic comments regarding this document to the Federal eRulemaking Portal at <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20857. Because multiple docket numbers are associated with this document, please include with your comments the docket number(s) that corresponds with the section of FDASIA and topic on which you are commenting (see table 2 of this document for a list of docket numbers and corresponding sections and topics). Comments that address more than one docket must be filed with each docket to ensure consideration. The deadline for submitting comments to the docket is August 12, 2013. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Table 2.--Docket Numbers for Each Section and Topic

Section of FDASIA	Topic	Docket No.
713	Standards for admission of imported drugs	FDA-2013-N-0683
714	Registration of commercial importers of drugs	FDA-2013-N-0684
714	Good importer practice	FDA-2013-N-0685

VI. Transcripts

Transcripts of the meeting will be available for review at the Division of Dockets Management and <http://www.regulations.gov> approximately 30 days after the meeting. A transcript will also be made available in either hardcopy or on CD-ROM, upon submission of a

Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: June 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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